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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: **PENN-0701**  
Inventors: **Alain H. Rook**  
Serial No.: **09/419,328**  
Filing Date: **October 15, 1999**  
Examiner: **D. Jiang**  
Group Art Unit: **1646**  
Title: **Methods for Treatment of Cutaneous T-Cell Lymphoma**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

DECLARATION OF ALAIN ROOK

I, Alain Rook hereby declare:

1. I am a co-author along with S.L. Gottlieb, J.T. Wolfe, B.R. Vowels, S.S. Sood, Z. Niu, S.R. Lessin and F.E. Fox of the paper entitled "Pathogenesis of cutaneous T-cell lymphoma: implications for the use of recombinant cytokines and photopheresis" published in Clinical Experimental Immunology in 1997.

2. I am the inventor of U.S. Patent Application Serial No. 09/419,328 filed October 15, 1999, which is based upon a provisional application 60/104,342 filed October 15, 1998. I am most familiar with the subject matter of this application and the research effort which lead to the discovery of the instant invention.

3. The above referenced paper on page 18, paragraph 2, states "At the time of this writing, phase I/II trials of recombinant IL-12 administered subcutaneously for CTCL have commenced at our institution." The Examiner in this case has stated that "Rook et al. disclose phase I/II clinical trials of recombinant IL-12 for treatment of cutaneous T cell lymphoma (CTCL), wherein IL-12 is administered subcutaneously". However, this paper does not disclose treatment of humans with IL-12, it was



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Page 2

not until after 1997 and the publication of the paper by Rook et al. that it was actually demonstrated that IL-12 was effective against CTCL. Although clinical trials were reported to be underway, they were only in the planning stages. Being that Phase I trials were still in planning stages, no patients had yet actually participated in the study. There was no evidence that IL-12 was effective against CTCL. In fact, initial studies administering IL-12 to cancer patients suffering with malignant melanoma resulted in no clinical response. Hence, IL-12 was not considered to be effective.

I hereby declare that all statements herein of our own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful statements and the like so made are punishable by fine or by imprisonment, or both, under \$1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the application, any patent issuing there upon, or any patent to which this verified statement is directed.

Alain H. Rook

7/31/01  
DATE